

REMARKS

I. Status of Claims

Claims 1-23 are pending.

Claims 1-23 stand rejected.

Claims 1 and 13 have been amended. No new matter has been added.

Claims 24 and 25 have been added. No new matter has been added.

Claims 12 and 23 have been cancelled.

II. Rejection under 35 USC §102

The examiner has rejected claims 1, 2 and 7 under 35 USC §102(b) as allegedly being anticipated by USP 4,573,996 to Kwiatek. It is the examiner's position that Kwiatek discloses each and every element of the claimed invention. The examiner has also rejected claims 1-3, 5 and 7 under 35 USC §102(b) as allegedly being anticipated by USP 4,695,465 to Kigasawa. It is the examiner's position that Kigasawa discloses each and every element of the claimed invention. The examiner has further rejected claims 1-3, 7 and 12 under 35 USC §102(b) as allegedly being anticipated by USP 4,952,402 to Sparks. It is the examiner's position that Sparks discloses each and every element of the claimed invention as recited in the claims. The examiner has also rejected claims 1-3, 5, 12-15 and 23 under 35 USC §102(b) as allegedly being anticipated by USP 5,380,747 to Medford. It is the examiner's position that Medford discloses each and every element of the claimed invention as recited in the claims.

Applicant respectfully disagrees with, and explicitly traverses, these rejections as none of the patents to Kwiatek, Kigasawa, Sparks, and Medford anticipate the present invention. A claim is anticipated only if each and every element recited therein is expressly or inherently

described in a single prior art reference. As will be shown, the cited references do not expressly or inherently describe each and every element recited in the claims.

However, in the interest of advancing the prosecution of this matter, applicant has amended independent claims 1 and 13 to more clearly state the invention. More specifically, applicant has amended claim 1 to positively recite that the device is biodegradable via the biodegradable carrier. Further both claims 1 and 13 have been amended to recite that the carrier is sized to circumferentially encompass the site. No new matter has been added. Support for the amendments to claims 1 and 13 may be found in claim 12 and in the written description in paragraph 22, which states, in part, "[t]he dimensions selected should be suitable for circumferentially placing the device 10 around a graft." Accordingly, no new matter has been added.

With regard to the Kwiatek reference, this reference discloses a device for the administration of an active agent to the skin or mucosa. The Kwiatek device includes an impermeable adhesive layer that surrounds a permeable adhesive layer to form a pocket so that the active agent can be released to the skin. The active agent cannot penetrate the impermeable adhesive layer. Kwiatek does not disclose that the device is biodegradable as is recited in claim 1 of the instant invention and therefore, does not disclose each and every element of claim 1. Accordingly, Kigasawa does not anticipate the subject matter of amended claim 1.

With regard to claims 2 and 7, these claims ultimately depend from and include the subject matter recited in claim 1, which has been shown to patentably distinguish over Kwiatek. For at least this reason, claims 2 and 7 also patentably distinguish over Kwiatek.

With regard to the Kigasawa reference, this reference discloses a device for the external application of a drug preparation through a soft patch having a stick-itself-to-the-skin property. The Kigasawa device includes a formulation of a desired drug in a tacky material that allows the

material to be externally applied and stick to a patient's skin. Kigasawa does not disclose that the device is biodegradable as is recited in claim 1 of the instant invention. In fact, Kigasawa appears to suggest that the device is not biodegradable as it "can be easily detached after use." (See col. 17, lines 59-60). Hence, claim 1, as amended, is patentably distinguishable over the Kigasawa reference, as Kigasawa does not disclose each and every element of the present invention. Accordingly, Kigasawa does not anticipate the subject matter of amended claim 1.

With regard to claims 2-3, 5 and 7, these claims ultimately depend from and include the subject matter recited in claim 1, which has been shown to patentably distinguish over Kigasawa. For at least this reason claims 2-3, 5 and 7 also patentably distinguish over Kigasawa.

With regard to the Sparks reference, this reference discloses a means of providing a controlled release of a powder and the process for its preparation. The Sparks reference includes references to means, such as suspension in liquid (col. 18, line 31), chewing gum (col. 19, lines 43), chewable tablets (col. 20, line 6), "melt" tablets (col. 20, line 4), and capsules (col. 21, line 6). Sparks does not disclose that the means is "sized to ... encompass the site" as is recited in claim 1 of the instant invention. Hence, Sparks does not disclose each and every element of claim 1. Accordingly, Sparks does not anticipate the subject matter of amended claim 1.

With regard to claims 1-3, and 7, these claims ultimately depend from and include the subject matter recited in claim 1, which has been shown to patentably distinguish over Sparks. For at least this reason, claims 1-3 and 7 also patentably distinguish over Sparks.

With regard to the Medford reference, this reference discloses a treatment for atherosclerosis and other cardiovascular and inflammatory disease. The treatment includes using dithiocarboxylates to block the induced expression of the endothelial cell surface adhesion molecule. The active ingredient is administered to the patient in "an acceptable carrier" (see col. 14, line 35), orally (see col. 14, line 51), intravenously (col. 14, line 56), tablets, pills, capsules,

troches (see col. 15, line 17). Medford does not disclose a carrier “sized to ... encompass the site” as is recited in amended claim 1. Hence, Medford does not disclose each and every element of amended claim 1. Accordingly, Medford does not anticipate the subject matter recited in amended claim 1.

With regard to claims 1-3, 5, and 12 (cancelled herein), these claims ultimately depend from and include the subject matter recited in claim 1, which has been shown to patentably distinguish over Medford. For at least this reason, claims 1-3, and 5 also patentably distinguish over Medford.

The examiner also states that Medford anticipates the method recited in independent claim 13. However, Medford does not expressly or inherently disclose a method including the step of administering at the graft site within the patient a vasodilator, incorporated into a biocompatible, biodegradable carrier sized to circumferentially encompass the graft site, as presently recited in claim 13. Hence, Medford does not anticipate the method recited in claim 13.

With regard to claims 14, 15, and 17 these claims ultimately depend from and include the subject matter recited in claim 13, which has been shown to patentably distinguish over Medford. For at least this reason, claims 14, 15, and 17 also patentably distinguish over Medford.

In view of the foregoing, Applicant respectfully requests reconsideration, withdrawal of the 35 USC §102(b) rejections.

III. Rejection Under 35 USC §103

The examiner has rejected claims 1-23 under 35 USC §103(a) as allegedly being unpatentable over Kwiatek ('996), Kigasawa ('465), Sparks ('402) and Medford ('747) all in view of Chen (USP 6,180,606). It is the examiner's position that “[t]he claims are drawn to a

device, which delivers vasodilating agents where the formulation comprises the agents and a biocompatible carrier. The carrier is biodegradable, and is recited to be methylcellulose or equine collagen. The agents are selected from well-known vasodilators such as nitroglycerine, and verapamil. Claims 13-23 are drawn to a method of delivering vasodilating agents using the device of the agent. ... The references do not however disclose the concentrations of the particular vasodilators present in the carriers ... As seen in Chen, which discloses the use of collagen as a biocompatible carrier composition, equine, human, bovine, and porcine or ovine collagen can be used and interchanged for the purposes of carrying an active agent.... It is the position of the examiner that due to the knowledge in the art as to the equivalency of these collagen sources for the purposes of active agent carrying, the selection of equine collagen does not impart patentability to the invention barring a showing of criticality to the particular source along with unexpected results of the choice. ... It would have been obvious .. to combine the teachings, knowledge and suggestions in the art, with an expected result of a method for delivering vasodilating agents to a patient along with a device, which optimizes the effectiveness of the agents.”

Applicant respectfully disagrees with, and explicitly traverses this rejection because the examiner has failed to establish a prima facie case of obviousness of the present invention. A claimed invention is prima facie obvious when three basic criteria are met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings therein. Second, there must be a reasonable expectation of success. And, third, the prior art reference or combined references must teach or suggest **all** the claim limitations (emphasis added).

With regard to claims 1 and 13, applicant has shown that none of the patents to Kwiatek, Kigasawa, Sparks, or Medford, discloses, suggests or teaches a biodegradable device including a biocompatible, biodegradable carrier incorporating a vasodilator wherein the carrier is sized to circumferentially encompass a site at which it is placed. Chen fails to cure the deficiencies of Kwiatek, Kigasawa, Sparks, and Medford, as Chen discloses compositions with enhanced osteogenic potential which relates to the repair, form and regeneration of bones, and in particular, teaches that the "composition ... can be produced in the form of a dehydrated sponge, powder, particles, membrane, fleece or fibers." (see col. 5, lines 12-13).

Further, the examiner admits that Kwiatek, Kigasawa, Sparks, and Medford, all in view of Chen still fail to teach or suggest all the elements of the claims. For example, the examiner states that "a skilled artisan would have been motivated to select the best collagen source...A skilled artisan would have been able to determine the best mode of disposal of the device...A skilled artisan also would have been able to determine the optimal duration of exposure to the device, through routine experimentation..." Accordingly, Kwiatek, Kigasawa, Sparks, and Medford, all in view of Chen fail to arrive at the present invention.

Additionally, the examiner does not provide any motivation for combining Kwiatek, Kigasawa, Sparks, Medford, and Chen, to arrive at the subject matter of the claims. The examiner merely concludes that a skilled artisan would have been motivated to do so. It is respectfully submitted that the only motivation for selecting the different features of Kwiatek, Kigasawa, Sparks, Medford, and Chen, to arrive at the subject matter of the claims comes from Applicant's own disclosure. Without the Applicant's disclosure, one of ordinary skill in the art would not have been motivated to reconstruct the claimed invention from Kwiatek, Kigasawa, Sparks, Medford, and Chen.

With regard to claims 2-11 and 14-22, these claims ultimately depend from and include all the subject matter of claims 1 and 13, respectively, which applicant has shown patentably distinguishes over Kwiatek, Kigasawa, Sparks, Medford, and Chen. For at least this reason, claims 2-11 and 14-22 patentably distinguish over Kwiatek, Kigasawa, Sparks, Medford, and Chen.

In view of the foregoing, Applicant respectfully requests reconsideration, withdrawal of the 35 USC §103(a) rejection.

IV. New Claims

Applicant has added new claims 24 and 25, which include the subject matter of the carrier being perforated. No new matter has been added. Support for these claims may be found in the written description on page 8, paragraph [0027] which states, in part, "[t]he device 10 may also include perforations 18 ... along the length thereof, which allows the surgeon or other medical personnel to remove a portion 10a of the device 10." It is respectfully submitted that the cited prior art fails to disclose, teach or suggest the subject matter of claims 24 and 25.

V. Summary

Applicants believe that all the Examiner's rejections under 35 U.S.C. §§ 102 and 103 have been addressed and overcome. None of the references, either alone, or in combination, anticipates or renders obvious the invention claimed. Accordingly, reconsideration, withdrawal of the rejections and allowance of the claims is respectfully requested.

If the examiner believes the prosecution of this application would be advanced by a telephone call, the examiner is invited to contact the applicant's attorney at the telephone number indicated below.

VI. Fees

A petition for a one-month extension to reply to the instant Office Action and a check to cover the cost of filing this petition are enclosed. No other fees are believed necessary. However, if there are any fees due and owed because of this Amendment and Response, or for other matters regarding this application, the examiner is authorized to charge such fees to Duane Morris LLP Deposit Account No. 50-2061.

Respectfully submitted,

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